

UNITED STATES DISTRICT COURT
DISTRICT COURT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING)	
PHARMACY, INC. PRODUCTS LIABILITY)	MDL No. 2419
LITIGATION)	Dkt. No. 1:113-md-2419 (FDS)
_____)	

**MOTION TO QUASH SUBPOENA AND OBJECTIONS OF NON-PARTY PAIN
CONSULTANTS OF WEST FLORIDA AND REQUEST TO APPEAR
TELEPHONICALLY AT STATUS CONFERENCE**

COMES NOW Non-Party Pain Consultants of West Florida ("PCWF"), having contemporaneously filed its Notice of Limited Appearance, files its Motion to Quash Plaintiffs' Steering Committee's ("PSC") Subpoena and Requests to Appear Telephonically at Status Conference, showing this Honorable Court as follows:

I. PRELIMINARY STATEMENT

The cases involved in this multidistrict litigation ("MDL") are about the harm caused by three specific lots of preservative-free methylprednisolone acetate ("MPA") produced and distributed by New England Compounding Pharmacy ("NECP") and injected after May 21, 2012. The PSC is now attempting to expand these cases to every single patient who received any single product in the past five years, which is evident by the scope and content of the numerous subpoenas PSC issued to non-parties, such as PCWF, and parties alike.

The CDC has defined the scope of the products tied to the fungal meningitis outbreak and the class of patients at risk, which are individuals who received an injection from the three specific lot numbers of NECP MPA after May 21, 2012.¹ To date, this encompasses about

¹ The Centers for Disease Control and Prevention ("CDC") defines a "probable case" of meningitis as "[a] person who received a preservative-free methylprednisolone acetate (MPA) injection, **with preservative-free MPA that definitely or likely came from one of the following three lots produced by the New England Compounding Center (NECC) [05212012@68, 06292012@26, 08102012@51]**, and subsequently developed..." certain identified conditions following an "...injection after May 21, 2012." Centers for Disease Control and Prevention, Case Definitions for Meningitis and Other Infections, http://www.cdc.gov/hai/outbreaks/clinicians/casedef_multistate_outbreak.html (last visited July 9, 2013) (emphasis in original).

13,500 people. As there is no evidence that the fungal meningitis outbreak is in any way linked to any NECP product other than the three specified lots of MPA, any discovery sought by PSC must be limited to the scope of these MDL cases: *the harm caused to Plaintiffs of this MDL who received a NECP MPA injection from a specified lot after May 21, 2012.*

Consequently, this Court should quash PSC's Subpoena, as neither PCWF nor any of its patients are named parties in this MDL. Further, the documents and information requested by the PSC – by subpoena or otherwise – far exceeds the time and scope related to the three specific lot numbers of NECP MPA. Therefore, if the Court orders any production of documents from PCWF in response to the Subpoena, it must be limited to the relevant timeframe and specified MPA lots, as any further requests are irrelevant, overly broad, and unduly burdensome.

II. PROCEDURAL HISTORY

On April 9, 2013, this Court appointed a group of attorneys to act as the Plaintiffs' Steering Committee, which, in regards to matters of discovery, was given the responsibility to initiate, coordinate, and conduct all pretrial discovery needed to prepare for the trial of this litigation on behalf of all plaintiffs.²

On June 21, 2013, this Court entered two Orders titled: "Order Granting Plaintiffs Leave to Serve Subpoenas and Qualified Protective Order Regarding Protection of Health Information" ("QPO") and "Order on Central Enforcement of Subpoenas" ("Enforcement Order").³ These Orders authorized Plaintiffs' Counsel to serve subpoenas on entities listed in New England NECP's Customer list.⁴

² Dkt. No. 82 ¶ 9.

³ Dkt. No. 192; Dkt. No. 193.

⁴ Dkt. No. 192 ¶ 1, 10.

Nevertheless, the Court limited the scope of PSC's Subpoena. For example, the QPO requires protected health information be produced to a third party vendor⁵ and limited to:

"the names of patients that have been identified as receiving NECP solutions, medications or compounds from January 2011 – November 2012, the patients' last known address, the records identifying that NECP was the supplier of the solution, medication or compound, including lot number, the hospital or healthcare facilities' NECP product purchase records, including order forms, prescriptions, billing and accounts receivable, the hospital or healthcare facilities' NECP product and storage and patient distribution records, and any other information that lead counsel and the PSC reasonable determine necessary to the prosecution or resolution of these actions."⁶ (emphasis added).

Further, the QPO states the documents, data, or other information produced pursuant to the Subpoena and Order shall be provided for the sole purpose of: "(i) investigating, litigating and resolving potential claims involved in this litigation; (ii) litigating and resolving potential claims in the chapter 11 case of NECP; and (iii) the administration of the Chapter 11 Case, and not for any other purpose."⁷ (emphasis added).

On July 8, 2013, counsel for PCWF, a non-party to this action, acknowledged service of PSC's Subpoena, which was issued from the United States District Court for the District of Massachusetts and signed by Mark Zamora of the Zamora Firm, in Atlanta, Georgia.⁸ The Subpoena Duces Tecum scheduled the deposition of a designated representative of PCWF to take place at the offices of PCWF on August 2, 2013 at 10:00 a.m. PCWF was listed as a recipient of NECP's solutions, medications compounds on NECP's Customer list. Attached to

⁵ Dkt. No. 192 ¶ 3.

⁶ Dkt. No. 192 ¶ 2.

⁷ Dkt. No.192 ¶ 6.

⁸ See, Acknowledgement of Service (attached hereto as Exhibit "A").

the Subpoena was a list of items the designated representative was to bring to the deposition which will be discussed in further detail below.⁹

Mr. Zamora and the undersigned conferred, and Mr. Zamora withdrew Requests 5, 11, 19, 20, and 21 of PSC's Subpoena. Although Mr. Zamora offered to marginally narrow the breadth of some of the remaining requests, an agreement among undersigned counsel and Mr. Zamora regarding the remaining requests could not be reached. Thus, PCWF objects to the remaining requests within PSC's Subpoena and moves this Court to quash the Subpoena, or in the alternative, enter a Protective Order for the reasons set forth below.

III. STANDARD OF REVIEW

This Court, under its MDL authority, has the power to issue, modify, and quash foreign-district subpoenas pursuant to 28 U.S.C. § 1407.¹⁰ When 28 U.S.C. § 1407(b) is the basis to issue a subpoena to a foreign district non-party deponent, the MDL sits as a judge of the district court where the deponent resides.¹¹ Thus, in regard to the Subpoena issued to PCWF, the Honorable Judge Saylor sits as a judge of the United States District Court for the Northern District of Florida and is bound by the precedent of the United States Eleventh Circuit Court of Appeals and Florida law.

IV. ARGUMENT AND CITATION OF AUTHORITY

PCWF objects to PSC's Subpoena in its entirety as the Subpoena failed to include the statutorily required fee with service of the Subpoena. PCWF further objects to the Subpoena in its entirety as it fails to comply with this Court's June 21, 2013 Orders (QPO and Enforcement

⁹ See, PSC Subpoena (attached hereto as Exhibit "B").

¹⁰ United States ex. Rel. Porgue v. Diabetes Treatment Centers of America, Inc., 444 F.3d 462, 468-69 (6th Cir. 2006).

¹¹ In re Seroquel Products Liability Litigation, 2008 WL 1995058 at *2 (S.D. Fla. 2012) (citing United States ex. Rel. Porgue v. Diabetes Treatment Centers of America, Inc., 444 F.3d 462, 467 (6th Cir. 2006)).

Order). PCWF also specifically objects to the requests within the Subpoena as unduly burdensome, overly broad, violative of HIPAA, wholly irrelevant, and otherwise objectionable as set forth below.

A. The Subpoena Should Be Quashed in its Entirety for Failure to Tender Witness Attendance Fees

PSC failed to provide PCWF with the \$40.00 fee required upon PCWF accepting service of the Subpoena. The plain language of Fed.R.Civ.P 45(b)(1) reads as follows:

(b) Service.

(1) By Whom; Tendering Fees; Serving a Copy of Certain Subpoenas. Any person who is at least 18 years old and not a party may serve a subpoena. Serving a subpoena requires delivering a copy to the named person and, if the subpoena requires that person's attendance, tendering the fees for 1 day's attendance and the mileage allowed by law. Fees and mileage need not be tendered when the subpoena issues on behalf of the United States or any of its officers or agencies. If the subpoena commands the production of documents, electronically stored information, or tangible things or the inspection of premises before trial, then before it is served, a notice must be served on each party.

(emphasis added).

PSC never formally served the Subpoena upon PCWF, although counsel for PCWF acknowledged service through e-mail on July 8, 2013.¹² Nevertheless, PSC still failed to provide the required witness fee, rendering the Subpoena invalid on its face and unenforceable. This Court should quash the Subpoena for failure to tender the required fees.

¹² Acknowledgement of Service, Exhibit A.

B. The Subpoena Should Be Quashed in its Entirety For Failure to Comply With This Court's Order

1. Breach of the January, 2011 – November, 2012, Timeframe

This Court's Enforcement Order permitted the issuance of subpoenas to non-parties. The same day this Court entered its Enforcement Order, the Court granted Plaintiffs leave to serve subpoenas and entered its QPO, which set out an up-front process for the subpoenaed entities to produce patients' Protected Health Information. The QPO limited the timeframe for PSC's subpoena requests to "the names of patients that have been identified as receiving NECP solutions, medications or compounds from January 2011 – November 2012. . ."¹³

Despite the clear direction from this Court in this Order, the majority of the Subpoena requests information regarding a five-year period from October 6, 2007 – October 6, 2012,¹⁴ while the remaining requests either provide no timeframe¹⁵ or information relating to 2010, 2011, 2012, and 2013.¹⁶ Because the Subpoena does not comply with this Court's Order, the Subpoena should be quashed.

2. The Court's Requirement that Protected Health Information Be Produced To A Vendor

PCS's subpoena violates this Court's QPO by requesting PCWF produce the documents and other information directly to PSC at the deposition.¹⁷ The QPO clearly stated that Protected Health Information shall be produced only to a third-party vendor.¹⁸ Despite this, PSC is attempting to require PCWF to turn this requested information over to Mark Zamora during the

¹³ Dkt. No. 192 ¶ 2.

¹⁴ PSC Subpoena, Exhibit B ¶ 1-4, 6-7, 9 (PCWF maintains this objection to ¶ 5 to extent it is not withdrawn).

¹⁵ PSC Subpoena, Exhibit B ¶ 8, 10, 12-16 ((PCWF maintains this objection to ¶ 11 to extent it is not withdrawn).

¹⁶ PSC Subpoena, Exhibit B ¶ 17-18 ((PCWF maintains this objection to ¶ 19 to extent it is not withdrawn).

¹⁷ PSC Subpoena, Exhibit B.

¹⁸ Dkt. No. 192 ¶ 3.

deposition that was scheduled to take place next month. As PSC has prematurely subpoenaed PCWF's records and failed to retain a Vendor, the Subpoena should be quashed.

3. Information Beyond the Scope of the QPO

PSC's subpoena exceeds the scope of the QPO, which stated, "the information requested and produced shall be limited to . . . and any other information that lead counsel and the PSC reasonably determine necessary to the prosecution and resolution of these actions . . . the documents, data, or other information produced pursuant to the subpoena shall be provided for the sole purpose of . . . investigating . . . potential claims involved in this litigation."¹⁹ (emphasis supplied).

Nevertheless, PSC seeks information well beyond the scope of the QPO and any investigation of the pending actions involved in the MDL, or as the Court described, this litigation or these actions. For example, PSC requested the identity and protected health information of PCWF's non-party patients²⁰, PCWF's corporate documents and insurance information²¹, and other information relating to PCWF's dealings with other non-party manufacturers and pharmacies²². These requests fall well outside this Court's QPO and PSC's duty to initiate, coordinate, and conduct the pretrial discovery needed to prepare for the trial of this litigation on behalf of all plaintiffs.²³ Thus, the Subpoena should be quashed as it is not limited to information necessary to the prosecution and resolution of the actions pending in the MDL, pursuant to this Court's Order.

¹⁹ Dkt. No. 192 ¶ 2, 3.

²⁰ PSC Subpoena, Exhibit B, ¶ 6.

²¹ PSC Subpoena, Exhibit B, ¶ 17-18 (PCWF maintains this objection to ¶ 19-21 to extent they are not withdrawn).

²² PSC Subpoena, Exhibit B, ¶ 2 (PCWF maintains this objection to ¶ 11 to extent it is not withdrawn).

²³ Dkt. No. 82 ¶ 9 (stating responsibility of PSC which includes investigating potential claims of Plaintiffs and not non-parties).

C. The Information Requested From PCWF is Overly Broad, Wholly Irrelevant, and Unduly Burdensome and Therefore Those Portions of the Subpoena Should Be Quashed

PCWF objects to the portions of the Subpoena which are irrelevant, overly broad, and unduly burdensome. A Court is required to quash or modify a subpoena if the subpoena subjects a person to undue burden. Fed. R. Civ. P. 45(c), in pertinent part, states:

(c) Protecting a Person Subject to a Subpoena.

(1) *Avoiding Undue Burden or Expense; Sanctions.* A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The issuing court must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

...

(3) *Quashing or Modifying a Subpoena.*

(A) *When Required.* On timely motion, the issuing court must quash or modify a subpoena that:

- (i) fails to allow a reasonable time to comply;
- (ii) requires a person who is neither a party nor a party's officer to travel more than 100 miles from where that person resides, is employed, or regularly transacts business in person—except that, subject to Rule 45(c)(3)(B)(iii), the person may be commanded to attend a trial by traveling from any such place within the state where the trial is held;
- (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
- (iv) subjects a person to undue burden.

In addition, Fed. R. Civ. P. 26(b)(2) in relevant part, provides:

[o]n motion or on its own, the court must limit the frequency or extent of discovery otherwise allowed by these rules or by local rule if it determines that ... (iii) the burden or expense of the proposed discovery outweighs its likely benefit, considering the needs of the case, the amount in controversy, the parties' resources, the importance of the issue at stake in the action and the importance of the discovery in resolving the issue.

(emphasis supplied).

1. Portions of the Subpoena Which Are Overly Broad and Seek Irrelevant Information Should be Quashed

First and foremost, PSC cannot meet its burden to establish its overly broad requests are relevant to the pending MDL.²⁴ The Federal Rules of discovery allow parties to subpoena information regarding any non-privileged matter that is relevant to any party's claim or defense.²⁵ Thus, the scope of discovery is not without limits, as a subpoena which requests completely irrelevant and/or overly broad information may be quashed or modified.²⁶

PSC's Subpoena requests are overly broad and irrelevant to the claims or defenses of the parties involved in the pending MDL. For example,²⁷ the protected health information, social security number, name, date of birth, address, and phone number of PCWF's non-party patients have no bearing on the parties' claims and defenses in the pending litigation.²⁸ Although the protected health information of plaintiffs who received treatment from PCWF and whose actions are pending the MDL would be relevant, the identity of non-party patients who were treated by a non-party healthcare provider is wholly irrelevant.²⁹

Similarly, PSC's requests for PCWF's insurance policies, articles of incorporation, or other business related documents have no bearing on the resolution of claims or defenses

²⁴ Fadalla v. Life Automotive Products, Inc., 2008 WL 68594 at *2 (M.D. Fla. 2008) (holding the party seeking discovery must demonstrate relevance).

²⁵ Fed. R. Civ. P. 26(b)(1); Commissariat A L'Energie Atomique v. Samsung Electronics Co., Ltd., 2006 WL 5003562 at *2 (M.D. Fla. 2006) (stating it is well settled that the scope of discovery under a subpoena is the same as the scope of discovery under Rule 26(b) and Rule 34).

²⁶ Bailey v. City of Daytona Beach, 286 F.D.R. 625 at 629 (M.D. Fla. 2012) (limiting the disclosure of plaintiff's personal health information to records which were germane to the issue before the court); Morris v. Sequa Corp., 275 F.R.D. 562, 567-69 (N.D. Ala. 2011) (limiting the disclosure of medical information to records which were relevant to the claims of the case after defendant subpoenaed records from plaintiff's non-party hospitals and physicians).

²⁷ These examples are intended to illustrate the reasons for the objection and not serve as an exclusive list

²⁸ PSC Subpoena, Exhibit B, ¶ 6.

²⁹ PCWF does not believe it has any patients in the MDL.

pending in MDL and are completely irrelevant.³⁰ For further example, the information requested regarding PCWF's dealings with other non-party facilities, manufacturers, and pharmacies, is overly broad and wholly irrelevant to PSC's claims in this MDL.³¹ Consequently, the Subpoena should be quashed and any future subpoena should be limited to information which is relevant to the actions pending in this MDL, pursuant to PSC's limited duty to conduct pretrial discovery needed to prepare for the trial of this litigation on behalf of all plaintiffs.³² (emphasis supplied).

2. PSC's Subpoena Will Subject PCWF to an Undue Burden and Should Be Quashed

In determining whether a subpoena causes "undue burden," the Federal courts weigh the burden to the subpoenaed party against the issuing party's interest in obtaining the information.³³ The somewhat limited case law concerning non-party production of discovery materials reveals there is a case-specific balancing test wherein the court weighs several factors: (1) relevance, (2) the need of the party for the documents, (3) the breadth of the document request, (4) the time period covered by the request, and (5) the particularity with which the documents described against the burden imposed on the person ordered to produce the desired information.³⁴ Further, the Court must also consider the status of a witness as a non-party when determining the degree of burden; the status of the person as a non-party is a factor often weighing against disclosure.³⁵

Thus, even if PSC could demonstrate the information requested is not overly broad or irrelevant, which PCWF argues it cannot, the Subpoena would still subject PCWF to an undue burden. PCWF's burden in producing the information, especially in light of its status as a non-

³⁰ PSC Subpoena, Exhibit B, ¶ 16-18 (PCWF maintains this objection to ¶ 19-21 to extent they are not withdrawn).

³¹ PSC Subpoena, Exhibit B, ¶ 2 (PCWF maintains this objection to ¶ 11 to extent it is not withdrawn).

³² Dkt. No. 82 ¶ 9 (stating responsibility of PSC).

³³ Maxwell v. Health Center of Lake City, Inc., 2006 WL 1627020 at *2 (S.D. Fla. 2006).

³⁴ Schaag v. SmithKline Beecham Corp., 2006 WL 2246146 at *2 (M.D. Fla. 2006).

³⁵ Id.

party, would far outweigh the Plaintiffs' minimal (if any) need or benefit in obtaining the documents for the following reasons:

First, as previously stated, PCWF is not a party to the action pending in the MDL nor are any of its patients, and all PSC's requests are irrelevant to the claims and defenses pending among the parties to that litigation. Thus, the requested documents will provide little (if any) benefit to Plaintiffs.

Second, the time period covered by PSC's requests are arbitrary and fall well beyond the scope of this Court's QPO which limited the timeframe to January, 2011 to November, 2012.³⁶ Despite PSC's representation to this Court in seeking the Order that this was the time period which would be requested of nonparties, PSC's request far exceed this Court's direct Order. Also, the CDC already defined the scope of the products tied to the fungal meningitis outbreak and the class of patients at risk, which are individuals who received an injection from the three specific lot numbers of NECP MPA after May 21, 2012. Therefore, PSC's requests are overly broad and seek information outside the scope of the relevant time period, as defined by the CDC, which began on May 21, 2012 and ended around the time of the recall, which was approximately September, 2012. As a result, PSC's requests will provide little (if any) benefit to Plaintiffs.

Third, the documents are broadly requested, as evidenced by the overlap of several requests. The requests also appear to have been sent to parties and non-parties alike, with no concern for the impropriety of treating a non-party like a party. By way of example, the Subpoena requests prescription forms for solutions that a pain clinic like PCWF would clearly not have in its possession, i.e. cardioplegic solution, ophthalmic solution and saline solution.³⁷

³⁶ Dkt. No. 192 ¶ 2.

³⁷ PSC Subpoena, Exhibit B ¶ 3-5.

Fourth, PCWF has a small support staff and complying with the Subpoena would require its daily operations to essentially shut down.³⁸ For example, to comply with Paragraph 6 of the Subpoena, PCWF would have to designate its limited resources to searching through its archives, three separate electronic medical record databases, paper charts, and a third party vendor billing records.³⁹ This does not include the additional time, effort and costs involved in complying with the other requests listed in the Subpoena, such as marketing materials or all communication and documents between PCWF and NECC, to name a few.

Thus, it would significantly burden PCWF, who is not even a party to this litigation, to comply with the Subpoena, while providing little benefit to the Plaintiffs. For these reasons, the Subpoena should be quashed to protect PCWF, a non-party, from the undue burden which would certainly result in complying with PSC's Subpoena.

D. The Documents Can Be Obtained From More Convenient Sources

Most of the documents requested by PSC are easily obtained from other, more appropriate sources. Fed. R. Civ. P. 26(c) permits the Court, for good cause, to issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense.⁴⁰ The party seeking the protective order has the burden to demonstrate good cause.⁴¹ In determining whether good cause exists, Federal courts may consider whether the discovery is more easily obtainable from some other source which is more convenient, less burdensome, or less expensive.⁴²

³⁸ See, Affidavit of Tamara Martin, ¶ 4 (Attached as Exhibit "C").

³⁹ Affidavit of Tamara Martin, Exhibit C, ¶ 5.

⁴⁰ Fed. R. Civ. P. 26(c).

⁴¹ Maxwell v. Health Center of Lake City, Inc., 2006 WL 1627020 at *2 (S.D. Fla. 2006).

⁴² Id. (citing Fed. R. Civ. P. 26(b)(2)).

PSC's requests should be directed to NECP, who is an actual party to the MDL, the Food and Drug Administration, the Center for Disease Control, or the Florida Department of Health, as these entities could more conveniently and efficiently produce the overwhelming majority of the documents requested. For example, the Subpoena requires PCWF to provide "marketing information from NECP, NECP's agents, or any sales company or person marketing, selling, or attempting to sell products on behalf of NECP."⁴³ However, any information regarding NECP and or their sales and marketing team can and should come directly from NECP. If Plaintiffs wish to obtain documents concerning any of NECP's sales agents, Plaintiffs should Subpoena the sales agents or NECP, both of which would be more appropriate than requesting such information from a non-party.⁴⁴

Thus, there is good cause to quash the Subpoena to protect PCWF, a non-party, from undue burden and expense. PCWF should not be required to spend considerable time and resources in complying with PSC's request when more convenient and less burdensome avenues exist for PSC to obtain the requested documents.

E. The Protected Health Information Sought By Plaintiffs is Protected By HIPAA And Therefore PCWF Should Not Be Required To Produce Such Information

Much of the information requested by Plaintiffs is Protected Health Information⁴⁵, and to provide this information to PSC would be violative of Health Insurance Portability and Accountability Act of 1996 ("HIPAA").⁴⁶

⁴³ PSC Subpoena, Exhibit B, ¶ 12.

⁴⁴ Other requests for documents which NECP, the FDA, the CDC, or the Florida Department of Health could more conveniently produce include but are not limited to: the procurement of MPA from NECP (Subpoena, ¶ 1); the procurement of cardioplegic solution from NECP (Subpoena, ¶ 3); the procurement of ophthalmic solution from NECP (Subpoena, ¶ 4); adverse event reports made to NECP (Subpoena, ¶ 8); documents relating NECP's qualifications, regulatory compliance, policies and procedures (Subpoena, ¶ 9); any communications to the CDC or FDA regarding NECP and other pharmacies (Subpoena, ¶ 10); any NECP agreements or warranties (Subpoena, ¶ 13); and any documents regarding NECP's recall notices and PCWF's responses (Subpoena, ¶ 14, 15).

⁴⁵ PSC Subpoena, Exhibit B, ¶ 6.

HIPAA requires a covered entity, such as PCWF, to keep patients' Protected Health Information confidential. Although a HIPAA exception permits the disclosure of such information through Court Order, or when the healthcare provider receives satisfactory assurance from the party seeking the information that reasonable efforts have been made to secure a "qualified protective order,"⁴⁷ a party is prohibited from using or disclosing the protected health information for any purpose other than the litigation or proceeding for which such information was requested.⁴⁸ (emphasis supplied). This coincides with the QPO, which states "the information requested and produced shall be limited to the names of patients that have been identified as receiving NECP solutions. . .and any other information that lead counsel and the PSC reasonable determine necessary to the prosecution or resolution of these actions."⁴⁹ (emphasis supplied).

Despite this Court's Order which limits the disclosure of protected health information to these actions, which PCWF interprets as the actions pending before the Honorable Judge Saylor and part of the MDL, PSC requests the protected health information of non-party patients from a non-party medical provider in an obvious attempt to obtain additional clients who are not involved in these actions or proceedings. Thus, the disclosure of the protected health information of PCWF's non-party patients would not fall within this Court's QPO and would be in violation of HIPAA.

Further, PSC's request for the identities of non-party patients is also prohibited by HIPAA, as the requested information will be disclosed to PSC for purposes of adding clients and initiating lawsuits, and not for the purposes of discovering relevant information pertinent to the

⁴⁶ 45 C.F.R. 164.501.

⁴⁷ 45 C.F.R. 160.103; 45 C.F.R. 164.512 (e)(1)(i-ii).

⁴⁸ 45 C.F.R. 164.512 (e)(1)(v); Fed. R. Civ. P. 45(c)(3)(A)(iii).

⁴⁹ Dkt. No. 192 ¶ 2.

these actions pending in the MDL proceedings. Thus, this Court must quash or modify the Subpoena to the extent it requires disclosure of protected health information of non-parties whose medical condition is not at issue in the MDL. The disclosure of non-parties protected health information falls outside the scope of this Court's QPO and would be in violation of HIPAA.⁵⁰

F. PSC's Attempt To Misuse The MDL Discovery Process For Its Fishing Expedition

PSC's request for the identities of PCWF's non-party patients is an obvious attempt to misuse and manipulate the MDL process for its fishing expedition of additional potential claimants. Multidistrict litigation and the discovery process is used "when civil actions involving one or more common questions of fact are pending in different districts," so that "such actions may be transferred to any district for coordinated or consolidated pretrial proceedings."⁵¹ (emphasis supplied). Thus, Federal law does not allow PSC to use the MDL discovery process to discover the identities of non-parties and investigate potential claims which are not pending.

Furthermore, the Supreme Court of the United States has held that when the purpose of a discovery request is to gather information for use in proceedings other than the pending suit, discovery is properly denied.⁵² In Oppenheimer Fund, Inc., v. Sanders, respondents brought a class action on behalf of shareholders to an investment fund.⁵³ Respondents sought to depose petitioner's employees and require petitioners to help compile a list of the names and addresses

⁵⁰ Estate of Carrillo v. F.D.I.C., 2012 WL 1831596 at *5 (S.D. Fla. 2012) (prohibiting all parties of subject law suit from using or disclosing any protected health information obtained pursuant to subpoenas duces tecum for any purpose other than the litigation of this lawsuit); Bailey v. City of Daytona Beach, 286 F.D.R. 625 at 629 (M.D. Fla. 2012) (limiting the disclosure of plaintiff's personal health information pursuant to HIPAA exception to records which were relevant, material, and germane to the issue before the court); Morris v. Sequa Corp., 275 F.R.D. 562, 567-69 (N.D. Ala. 2011) (limiting the disclosure of medical information to records which were relevant to the claims of the case after defendant subpoenaed records from plaintiff's non-party hospitals and physicians).

⁵¹ 28 U.S.C.A. § 1407.

⁵² Oppenheimer Fund, Inc. v. Sanders, 437 U.S. 340 (1978).

⁵³ Oppenheimer Fund, Inc. v. Sanders, 437 U.S. 340 (1978).

of the members of the plaintiff class from records kept by the respondent's employees, so that individual notice could be sent to those who were not yet parties to the action.⁵⁴

Nevertheless, the Supreme Court stated the respondent's attempt to obtain the class members' names and addresses could not be forced into the concept of "relevancy," pursuant to Rule 26(b)(1).⁵⁵ The Court held the names and addresses were not relevant to the subject matter involved in the pending litigation simply because respondents needed the information in order to send the class notice.⁵⁶ Further, the Court stated it could not perceive any "potential issues" that could bring respondent's request within the scope of legitimate discovery, as any potential issues could not arise until respondents obtained the very information which they sought.⁵⁷

The circumstances at bar are even further removed from Oppenheimer, as no class action has been filed, and therefore, the identity of PCWF's non-party patients has even less of a connection to the individual and independent claims brought by Plaintiffs across the country against NECP and other named Defendants.

Nevertheless, PSC seeks to use MDL discovery proceedings for the exact reasons which Oppenheimer forbids, which is to discover the identities and addresses of non-parties in an attempt to notice or add clients. Similar to Oppenheimer, PSC's discovery request to a non-party provider for the identities, addresses, and other protected health information of non-party patients cannot be forced into the definition of "relevancy," as such information has no bearing on the individual actions pending in MDL. As a result, the Subpoena should be quashed to the extent PSC attempts to misuse the MDL discovery process to obtain non-party protected health

⁵⁴ Id.

⁵⁵ Id. at 351-52.

⁵⁶ Id. at 353-54.

⁵⁷ Id. at 354.

information in order to add clients or later sue the non-parties who provided the confidential information.

G. The Subpoena Should Be Modified To Allow A Reasonable Period of Time to Comply

Even if these requests were not objectionable for all of the reasons set forth above, PSC failed to provide PCWF a reasonable period of time to comply with its requests for documents.⁵⁸ PCWF acknowledged service for PSC's Subpoena on July 8, 2013, after PSC failed to formally serve PCWF.⁵⁹ The Subpoena scheduled the deposition of a designated representative of PCWF to occur at the offices of PCWF on August 2, 2013. This is far too short of a timeframe to comply with the unduly burdensome requests propounded by PSC, as PCWF has limited resources to designate for PSC's overly broad requests. If the Court is inclined to rule that PCWF has to comply with even some of these requests, PCWF respectfully requests this Court modify the Subpoena to allow PCWF a reasonable period to comply. The time necessary would be dependent on the time and scope of the requests.

V. INDIVIDUAL OBJECTIONS

Cumulative to the preceding objections, PCWF hereby incorporates by reference its individual objections to each portion of the Subpoena which were discussed with Mark Zamora and sent to him by letter, attached hereto as Exhibit "D".⁶⁰ As previously stated, Mr. Zamora agreed to withdraw Subpoena Requests 5, 11, 19, 20, and 21, but PCWF maintains its specific objections to the remaining requests which were not withdrawn.

⁵⁸ Fed. R. Civ. P. 34(b)(2)(A) and 45(c)(3)(A)(i).

⁵⁹ Acknowledgement of Service, Exhibit A.

⁶⁰ See, Letter to Mark Zamora, dated July 15, 2013 (Attached as Exhibit "D").

VI. REQUEST TO APPEAR AT STATUS CONFERENCE TELEPHONICALLY

Counsel for PCWF is located in Tallahassee, Florida. It would be expensive and difficult for counsel for PCWF to travel to Boston, Massachusetts for the July 18, 2013 status conference. As such, PCWF requests that their counsel be allowed to appear at the status conference telephonically and for the Court to hear PCWF's objections to the Subpoena at that time.

VII. CONCLUSION

For all the above-stated reasons, PCWF respectfully requests this Court quash or significantly modify the Subpoena, or in the alternative, enter a protective order, in accord with PCWF's objections and allow PCWF's counsel to appear telephonically at the Status Conference.

Respectfully submitted,

FULLER, MITCHELL, HOOD &
STEPHENS, LLC

/s/ Halley M. Stephens

HALLEY M. STEPHENS

Fla. Bar No.: 0154725

hstephens@fmhslaw.com

2565 Barrington Circle

Tallahassee, FL 32308

TELEPHONE: (850) 222-0770

FACSIMILE: (850) 222-0760

*Attorneys for Non-Party Pain Consultants
of West Florida*

CERTIFICATE OF COUNSEL

Pursuant to Loc. R. 7.1 of this Court, the undersigned has conferred with Mark Zamora of PSC in a good faith effort to resolve the issues raised PCWF's Motion to Quash Subpoena and Objections, but was unsuccessful.

Dated: July 16, 2013.

/s/ Halley M. Stephens
Halley M. Stephens

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that I caused a copy of the above Objections and Motion to Quash Plaintiffs' Steering Committee's Subpoena to be filed electronically on the 16th of July, 2013, via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

/s/ Halley M. Stephens
Halley M. Stephens

Halley Stephens

From: mark@markzamora.com
Sent: Monday, July 08, 2013 11:55 AM
To: Halley Stephens
Cc: Dan Cauley
Subject: RE: NECC and your client

Understood. Let's keep the SDT with the stated date on it. We are required to meet and confer on proposed objections so as to work out as many of them as possible. Please let me know what day and time this week would work best for you for the M&C.

Mark Zamora, Attorney
Zamora Firm
6 Concourse Parkway, 22nd Floor
Atlanta, GA 30328
Tel: 404.451.7781
FAX: 404.506.9223
Licensed in GA & FL
email: mark@markzamora.com

----- Original Message -----

Subject: RE: NECC and your client
From: Halley Stephens <HStephens@fmhslaw.com>
Date: Mon, July 08, 2013 10:37 am
To: "mark@markzamora.com" <mark@markzamora.com>
Cc: Dan Cauley <dcauley@fmhslaw.com>

Mark,

I am just going to accept service as of today because I need to file objections by the upcoming deadline.

Thanks.

Halley

From: mark@markzamora.com [<mailto:mark@markzamora.com>]
Sent: Monday, July 08, 2013 10:35 AM
To: Halley Stephens
Subject: RE: NECC and your client

You did not tell me that before today. If you are not willing to acknowledge service, would you be willing to give me a proposed date for the records custodian deposition? How does August 1, 2013 sound?

Mark Zamora, Attorney
Zamora Firm
6 Concourse Parkway, 22nd Floor
Atlanta, GA 30328
Tel: 404.451.7781
FAX: 404.506.9223



Licensed in GA & FL
email: mark@markzamora.com

----- Original Message -----

Subject: RE: NECC and your client
From: Halley Stephens <HStephens@fmhslaw.com>
Date: Mon, July 08, 2013 9:36 am
To: "mark@markzamora.com" <mark@markzamora.com>

Did you ever formerly serve my client with the subpoena? I wanted to make sure before we filed something with the Court. I have not been authorized to accept service on their behalf. Thanks.

From: mark@markzamora.com [<mailto:mark@markzamora.com>]
Sent: Tuesday, July 02, 2013 1:52 PM
To: Halley Stephens
Subject: NECC and your client

Hi Halley:

Here is the Order relating to documents other than HIPAA protected records. Please call me Monday if possible.

Mark Zamora, Attorney
Zamora Firm
6 Concourse Parkway, 22nd Floor
Atlanta, GA 30328
Tel: 404.451.7781
FAX: 404.506.9223

Licensed in GA & FL
email: mark@markzamora.com

AO 88A (Rev. 06/09) Subpoena to Testify at a Deposition in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Massachusetts

In re: New England Compounding Pharmacy

Plaintiff

v.

Applies to all Cases

Defendant

Civil Action No. MDL 1:13-md-02419

(If the action is pending in another district, state where:

SUBPOENA TO TESTIFY AT A DEPOSITION IN A CIVIL ACTION

To: Pain Consultants of West Florida, P.A. via its Registered Agent Kurt Krueger, M.D.
4624 N. Davis Highway, Pensacola, FL 32503

☒ **Testimony:** YOU ARE COMMANDED to appear at the time, date, and place set forth below to testify at a deposition to be taken in this civil action. If you are an organization that is *not* a party in this case, you must designate one or more officers, directors, or managing agents, or designate other persons who consent to testify on your behalf about the following matters, or those set forth in an attachment:
See Deposition Notice and Exhibit A

Place: 4624 North Davis Highway, Pensacola FL 32503

Date and Time:

08/02/2013 10:00 am

The deposition will be recorded by this method: Stenographically and Videographically

☒ **Production:** You, or your representatives, must also bring with you to the deposition the following documents, electronically stored information, or objects, and permit their inspection, copying, testing, or sampling of the material:

See attached Exhibit

The provisions of Fed. R. Civ. P. 45(c), relating to your protection as a person subject to a subpoena, and Rule 45 (d) and (e), relating to your duty to respond to this subpoena and the potential consequences of not doing so, are attached.

Date:

6/20/13

CLERK OF COURT

OR

Signature of Clerk or Deputy Clerk

Attorney's signature

The name, address, e-mail, and telephone number of the attorney representing (name of party)

Plaintiffs' Steering Committee

MARK ZAMORA, 6 Concourse Parkway, 22nd Floor, Atlanta, GA 30328/

, who issues or requests this subpoena, are:

DEFENDANT'S
EXHIBIT

B

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND)	
COMPOUNDING PHARMACY, INC.)	MDL No. 1:13-md-02419
PRODUCTS LIABILITY LITIGATION)	
)	Hon. F. Dennis Saylor, IV
This Document Relates To: All Cases)	
_____)	

**NOTICE OF TAKING VIDEOTAPED ORAL DEPOSITION
OF DESIGNATED REPRESENTATIVE(S) OF NON PARTY**

Please take notice that on August 2, 2013 beginning at 10:00 A.M. at the offices of PAIN CONSULTANTS OF WEST FLORIDA the deposition of a designated corporate representative will be taken upon oral examination by one or more attorneys of the Plaintiffs' Steering Committee in the pending MDL, pursuant to Rule 30 of the Federal Rules of Civil Procedure for the purpose of discovery or for use as evidence in this action, and before an officer authorized by law to administer oaths.

PLEASE TAKE FURTHER NOTICE that pursuant to Rules 30 and 34 of the Federal Rules of Civil Procedure, the non-party deponent(s) shall produce at the deposition the documents identified in Exhibit 1 attached to this Notice.

Duty to designate. By designating a representative, the organization indicates its representative has the authority to speak on its behalf about the matters listed in this deposition notice – not only to facts, but also to subject beliefs and opinions.¹

¹ *Lapenna v. Upjohn Co.*, 110 F.R.D. 15, 20 (E.D. Pa. 1986); *See also Alexander v. Fed. Bureau of Investigation*, 186 F.R.D. 148, 151-52 (D.D.C. 1999); *Mitsui & Co. v. Puerto Rico Water Res. Autho.*, 93 F.R.D. 62, 66-67 (D.P.R. 1981).

Duty to substitute. If it becomes clear that the chosen representative is unable to respond to questions on the matters for which he or she has been designated, the organization must immediately provide a substitute knowledgeable witness. This is required even if the initial designation was made in good faith.²

Duty to prepare. The testimony elicited in the deposition represents the organization's knowledge, not the individual deponent's knowledge. The organization must conduct a thorough investigation in response to the deposition notice and must prepare any witness to testify to all matters "known or reasonably available to the organization." Therefore, if the organization's designee is not knowledgeable about the matters specified in the deposition notice, it must nonetheless prepare such designee to give knowledgeable, binding answers.³

"Reasonably available" information includes all documents that the organization has the authority, legal right, or practical ability to obtain. An inadequately prepared designated witness will amount to an impermissible refusal to answer and a sanctionable failure to appear.⁴

Scope of inquiry The description contained in the deposition notice simply identifies the minimum to which a witness must be prepared to testify. If an examining

² See *Marker v. Union Fidelity Life*, 125 F.R.D. 121, 126 (M.D.N.C. 1989).

³ *United States v. Taylor*, 166 F.R.D. 356, 361 (M.D.N.C. 1996) .

⁴ *Prokosch v. Catalina Lighting, Inc.*, 193 F.R.D. 633, 637 (D. Minn. 2000) (citing *Lumber v. PPG Industries, Inc.*, 168 F.R.D. 641, 643 n. 1 (D. Minn. 1966); See *Black Horse Lane Assoc., L.P. v. Down Chem. Corp.*, 228 F. 3d 275, 303-04 (3d Cir. 2000); *Resolution Trust Corp. v. S. Union Co.*, 985 F. 2d 196, 197 (5th Cir. 1993); *Taylor*, 166 F.R.D. at 363; *Marker v. Union Fidelity Life Ins. Co.*, 125 F.R.D. 121, 126 (M.D.N.C. 1989).

party asks questions outside the scope of the matters described in the notice, the general deposition rules govern.

DESIGNATION OF TESTIMONY AND PRODUCTION OF DOCUMENTS

The designated matters upon which examination is requested are as follows:

1. To provide testimony regarding those individuals involved in the production of documents.
2. To provide testimony regarding the efforts made and the time expended in the production of documents.
3. To provide testimony regarding the methods of search and methods of production of documents produced.
4. To provide testimony regarding the authenticity of documents.
5. To provide testimony regarding the methods of storage, entry and use of computer data and the method by which it has been produced.
6. To provide testimony regarding the location and methods of storage of corporate documents.
7. To provide testimony regarding the existence of documents.
8. To provide testimony regarding the electronic creation, duplication and/or storage of the documents.
9. To provide testimony regarding any and all document retention/destruction policies that would relate to any of the documents.
10. To provide testimony regarding the searchability of databases for the extraction of information.

Dated: June 20, 2013

/s/ Mark Zamora
Mark Zamora
ZAMORA FIRM
6 Concourse Parkway, 22nd Floor
Atlanta, GA 30328
Phone: (404) 451-7781
Fax: (404) 506-9223
mark@markzamora.com
Plaintiffs' Steering Committee

CERTIFICATE OF SERVICE

I, MARK ZAMORA, hereby certify that I caused a copy of the foregoing to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Dated: June 20, 2013
/s/ Mark Zamora
Plaintiffs' Steering Committee

Exhibit A to Subpoena

1. Any and all documents and/or electronically stored information ("ESI") reflecting, and/or related in any way whatsoever to, the procurement of methylprednisolone acetate ("MPA") and any other injectable steroid preparations from New England Compounding Pharmacy, Inc. ("NECP") during the five-year period immediately preceding October 6, 2012, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of steroid preparation, the cost you paid for the steroid preparation, applicable warranties, shelf life, expiration dates, requirements and instructions for shipment and/or storage, and the specific identity of the preparation being purchased. Also including account information, prescriptions submitted to NECP, prescription order forms, NECP charges for MPA (before and after any discounts applied).

2. Any and all documents and/or ESI reflecting, and/or related in any way whatsoever to, the procurement of MPA, or its generic or name-brand equivalent, from any producer, compounding facility or manufacturer other than NECP, since October 6, 2007, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of the product, the cost you paid for the product, applicable warranties, shelf life, expiration dates, requirements and instructions for shipment and/or storage, and the specific identity of the preparation being purchased.

3. Any and all documents and/or ESI reflecting, and/or related in any way whatsoever to, the procurement of cardioplegic solution from NECP during the five-year period immediately preceding October 6, 2012, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of cardioplegic solution, the cost you paid for the cardioplegic solution, applicable warranties, shelf life, expiration dates, and requirements and instructions for shipment and/or storage. Also including prescriptions submitted to NECP, prescription order forms, NECP charges for cardioplegic solution (before and after any discounts applied).

4. Any and all documents and/or ESI reflecting, and/or related in any way whatsoever to, the procurement of ophthalmic solution from NECP during the five-year period immediately preceding October 6, 2012, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of ophthalmic solution, the cost you paid for the ophthalmic solution, applicable warranties, shelf life, expiration dates, and requirements and instructions for shipment and/or storage. Also including prescriptions submitted to NECP, prescription order forms, NECP charges for ophthalmic solution (before and after any discounts applied).

5. Any and all documents and/or ESI reflecting, and/or related in any way whatsoever to, the procurement of preservative-free saline solution from NECP during the five-year period immediately preceding October 6, 2012, including without limitation of the

foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of saline solution, the cost you paid for the saline solution, applicable warranties, shelf life, expiration dates, and requirement and instructions for shipment and/or storage. Also including prescriptions submitted to NECP, prescription order forms, NECP charges for preservative-free saline solution (before and after any discounts applied).

6. Any and all documents and/or ESI reflecting, and/or related to, the identification of each and every patient that was administered an NECP product during the five-year period immediately preceding October 6, 2012, including patient name, address, date of birth, identification of product administered, and date product was administered.

7. Any and all documents and/or ESI reflecting or containing communications (written or otherwise) between PAIN CONSULTANTS OF WEST FLORIDA (Healthcare Provider"), its employees, principals, partners, and/or agents, and NECP, its employees and/or agents, during the five-year period immediately preceding October 6, 2012, including, but not limited to, any complaints or adverse event reports made to NECP by the Healthcare Provider.

8. Any and all documents and/or ESI reflecting or containing information obtained by the Healthcare Provider, its employees and/or agents, regarding NECP, including without limitation of the foregoing, NECP's qualifications, certifications or accreditations, or lack thereof, regulatory compliance, lack of regulatory compliance, operations, enforcement actions, suitability for conducting its business, legal actions and/or warnings, brochures, policies and procedures, ordering and delivery information company overviews, standard operating procedures, executive summaries, attachments A, B or others (relating to HIPAA, NECP policies and procedures, or other information).

9. Any and all documents and/or ESI reflecting or containing information obtained by, or communications received by, the Healthcare Provider, its employees and/or agents, concerning the fitness of any products purchased or obtained from NECP for their intended use, during the five-year period immediately preceding October 6, 2012, including but not limited to any environmental testing results, microbiology reports or certificates of analysis.

10. Any and all documents and/or ESI reflecting or containing information obtained by, or sent to, the Healthcare Provider, its employees and/or agents, from the Centers for Disease Control and Prevention, the Federal Food and Drug Administration, and/or any other Federal, state or local regulatory agency, concerning the fitness of any products manufactured, compounded or produced by NECP for their intended purpose.

11. Any and all documents and/or ESI reflecting or containing communications between the Healthcare Provider and any federal or state agency (including, but not limited to state licensing authorities, the Food and Drug Administration, and the Centers for Disease Control and Prevention) in connection with the procurement of products from any compounding pharmacy.

12. Any and all documents and/or ESI reflecting or containing marketing information from NECP, NECP's agents, or any sales company or person marketing, selling, or attempting to sell products on behalf of NECP.

13. Any and all documents and/or ESI reflecting or containing agreements, contracts and/or warranties between the Healthcare Provider and NECP, NECP's agents, or any sales company or person marketing, selling, or attempting to sell products on behalf of NECP.

14. Any and all documents and/or ESI reflecting or containing recall notices received by the Healthcare Provider pertaining to products produced by NECP, including without limitation of the foregoing, the date, time and manner of receipt of the recall notices, the specific person or persons within the Healthcare Provider who received the notice, and the substance of the notice.

15. Any and all documents and/or ESI reflecting or containing communications made or issued by the Healthcare Provider, its employees and/or agents, in response to any recall notice regarding NECP products, including without limitation of the foregoing, the date, time and manner of transmission of the communication, the person(s) to which the communication was directed, and the person at the Healthcare Provider who made or delivered the communication.

16. Any and all documents regarding any investigation or inquiry the Healthcare Provider performed related to attempts by NECP to comply with UPS 797.

17. Any and all policies of insurance, including without limitation of the foregoing, professional liability, malpractice, products liability, general liability, and comprehensive or umbrella policies, issued to the Healthcare Provider and/or its principal officers and directors and/or any physician working for or on behalf of the Healthcare Provider, for the policy periods including calendar years 2011, 2012 and 2013.

18. Articles of Incorporation and/or By-Laws applicable to the Healthcare Provider for calendar years 2011, 2012 and 2013.

19. Any and all documents and/or ESI reflecting or containing the names, addresses and positions (President, Vice-President, Director, etc.) within the Healthcare Provider of all officers and directors of the Healthcare Provider during the calendar years 2011, 2012 and 2013.

20. Any and all documents showing the entities or individuals with an ownership interest in the Healthcare Provider.

21. Any and all organizational charts maintained by the Healthcare Provider and/or any documents listing directors, officers, employees, and/or agents of the Healthcare Provider showing the names and positions of said directors, officers, employees, and/or agents and their relationship or rank within the Healthcare Provider.

AFFIDAVIT OF TAMARA MARTIN

STATE OF FLORIDA
COUNTY OF ESCAMBIA

BEFORE ME, the undersigned authority, personally appeared, Tamara Martin, who being first duly sworn, deposes and says:

1. I am Tamara Martin, and I have personal knowledge of the facts stated in this Declaration. I am over the age of 18, and I am of sound mind and body and otherwise competent to testify about the matters stated in this Declaration.
2. I am employed by Pain Consultants of West Florida as Practice Manager and have held this position for approximately 2 years.
3. I have reviewed the subpoena issued by the Plaintiffs' Steering Committee, specifically the document requests listed as an exhibit to this subpoena.
4. My office would be unable to comply with this subpoena in the time period designated, which would be the deposition date of August 2, 2013. Pain Consultants of West Florida has a front office staff of 9 employees. I would estimate that we would need at least 4 employees working full time on this project in an effort to comply with this request which would essentially shut down our daily operations until completed at a significant cost to the clinic.
5. It is difficult to even estimate how long it would take to gather the documents requested that we do have in our possession. For example, in order to comply with the patient name list request alone for the designated time period, a review of archives, three separate EMR databases, all paper charts and third party vendor billing records would need to be completed. See Subpoena, Request # 6.
6. I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

FURTHER AFFIANT SAYETH NAUGHT.



Tamara Martin

Sworn to and subscribed to before me by Tamara Martin [] who is personally known to me OR [✓] who produced FLDL as identification, this 15 day of July, 2013.


NOTARY PUBLIC

My Commission Expires: Jan 9, 2017



Con

FULLER, MITCHELL, HOOD & STEPHENS, LLC
LAWYERS

S. WILLIAM FULLER, JR.
P. SCOTT MITCHELL *
KATHRYN L. HOOD
HALLEY M. STEPHENS
DANIEL P. CAULEY

*Florida Bar Certified Circuit Mediator

2565 BARRINGTON CIRCLE
TALLAHASSEE, FLORIDA 32308
TELEPHONE 850.222.0770
FACSIMILE 850.222.0760

July 15, 2013

Mark Zamora, Esq.
6 Concourse Parkway, 22nd Floor
Atlanta, GA 30328

*Via E-mail - mark@markzamora.com
and Facsimile - 404.506.9223*

Re: New England Compounding Pharmacy, Inc. Products Liability Litigation

Dear Mr. Zamora:

We represent Pain Consultants of West Florida ("PCWF") and this letter is responsive to the subpoena duces tecum ("Subpoena") issued on June 20, 2013 and accepted by us on July 8, 2013. On behalf of PCWF we object to this subpoena on the grounds that the requests seek information which is wholly irrelevant to this litigation as PCWF is not a party to this litigation, nor are any of its patients, it is overly broad, exceeds the scope of the Court's Orders (Order Granting Plaintiffs Leave to Serve Subpoenas and Qualified Protective Order), seeks information which can be more conveniently produced by other sources, and constitutes an undue burden on our client, who is a non-party to this MDL. Further, even if we did not object to the requests contained in your subpoena, it would be impossible to even attempt to comply with these requests by the deadline of August 2, 2013. We ask that you withdraw this subpoena, or we will have no choice but to file a Motion to Quash.

The individual objections to the requests contained in Exhibit A to Subpoena are as follows:

- ¶1 Any and all documents and/or electronically stored information ("ESI") reflecting, and/or related in any way whatsoever to, the procurement of methylprednisolone acetate ("MPA") and any other injectable steroid preparations from New England Compounding Pharmacy, Inc. ("NECP") during the five-year period immediately preceding October 6, 2012, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of steroid preparation, the cost you paid for the steroid preparation, applicable warranties, shelf life, expiration dates, requirements and instructions for shipment and/or storage, and the specific identity of the preparation being purchased. Also including account information,



Mark Zamora, Esq.
July 15, 2013
Page 2

prescriptions submitted to the NECP, prescription order forms,
NECP charges for MPA (before and after any discounts applied).

OBJECTION: PCWF objects to Request No. 1 on the grounds that:

This request to a non-party is irrelevant to the pending claims or defenses between named parties in the MDL;

The request is overly broad as it seeks information beyond the relevant time, scope and subject matter of this litigation established by Centers for Disease Control and Prevention ("CDC"), which has defined the patients at risk and the products tied to the fungal meningitis outbreak to those patients injected after May 21, 2012 with three specific lots of methylprednisolone acetate ("MPA") – Lot Numbers 05212012@68, 06292012@26, and 08102012@51 – produced by the New England Compounding Center ("NECC");

The request exceeds this Court's Order which limited the Subpoena in time (January 2011 – November 2012) and scope (information relating to "these actions");

PCWF further objects to this Request to the extent it seeks documents that are not in PCWF's ownership, possession, custody or control, or that would require it to seek documents from or belonging to third parties.

PCWF further objects to the extent the documents and information the PSC seeks can be obtained from some other source that is more convenient, less burdensome, and/or less expensive, such as NECP, who is a party to the MDL.

PCWF further objects to this Request to the extent it fails to define various vague and ambiguous terms and conditions including, but not limited to "procurement," "injectable steroid preparations," "specific identity of the preparation being purchased," and "discounts applied."

PCWF further objects to the production of ESI that is not reasonably accessible or would otherwise impose undue burden or cost to identify, collect, process, review and/or produce.

In addition, PCWF objects to the extent the PSC seeks the production of ESI without: (1) any negotiated ESI protocol; (2) providing necessary clarification and appropriate limitations as to the type(s), location(s), and accessibility of the ESI requested; and/or (3) including any good-faith proposal for appropriate cost-shifting relative to PCWF's identification, collection, review and production.

PCWF further objects to this Request to the extent it seeks to force PCWF to conduct an unreasonable, unduly burdensome search, review and production on the PSC's behalf.

Mark Zamora, Esq.
July 15, 2013
Page 3

¶2 Any and all documents and/or ESI reflecting, and/or related in any way whatsoever to, the procurement of MPA, or its generic or name-brand equivalent, from any producer, compounding facility or manufacturer other than NECP, since October 6, 2007, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of the product, the cost you paid for the product applicable warranties, shelf life, expiration dates, requirements and instructions for the shipment and/or storage and the specific identity of the preparations being purchased.

OBJECTION: PCWF objects to ¶2 on the grounds that:

The information requested regarding non-party PCWF's purchases from other non-party producers, facilities, or manufacturers is overly broad and wholly irrelevant to parties' pending claims and defenses in this MDL;

The request is overly broad as it seeks information beyond the relevant time, scope and subject matter of this litigation established by Centers for Disease Control and Prevention ("CDC"), which has defined the patients at risk and the products tied to the fungal meningitis outbreak to those patients injected after May 21, 2012 with three specific lots of methylprednisolone acetate ("MPA") – Lot Numbers 05212012@68, 06292012@26, and 08102012@51 – produced by the New England Compounding Center ("NECC");

The request exceeds this Court's Order which limited the Subpoena in time (January 2011 – November 2012) and scope (information relating to "these actions");

PCWF further objects to this Request to the extent it seeks documents that are not in PCWF's ownership, possession, custody or control, or that would require it to seek documents from or belonging to third parties.

PCWF further objects to the extent the documents and information the PSC seeks can be obtained from some other source that is more convenient, less burdensome, and/or less expensive.

PCWF further objects to this Request to the extent it fails to define various vague and ambiguous terms and conditions including, but not limited to "procurement," "generic," "name-brand equivalent," and "specific identity of the preparation being purchased."

PCWF further objects to the production of ESI that is not reasonably accessible or would otherwise impose undue burden or cost to identify, collect, process, review and/or produce. In addition, PCWF objects to the extent the PSC seeks the production of ESI without: (1)

Mark Zamora, Esq.
July 15, 2013
Page 4

any negotiated ESI protocol; (2) providing necessary clarification and appropriate limitations as to the type(s), location(s), and accessibility of the ESI requested; and/or (3) including any good-faith proposal for appropriate cost-shifting relative to PCWF's identification, collection, review and production.

PCWF further objects to this Request to the extent it seeks to force PCWF to conduct an unreasonable, unduly burdensome search, review and production on the PSC's behalf.

¶3 Any and all documents and/or ESI reflecting, and/or related in any way whatsoever to, the procurement of cardioplegic solution from NECP during the five-year period immediately preceding October 6, 2012, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of cardioplegic solution, the cost you paid for the cardioplegic solution, applicable warranties, shelf life, expiration dates, and requirements and instructions for shipment and/or storage. Also including prescriptions submitted to NECP, prescription order forms, NECP charges for cardioplegic solution (before and after any discounts applied).

As discussed, my client, as a pain clinic, does not use cardioplegic solution.

OBJECTION: PCWF objects to ¶3 on the grounds that:

This request to a non-party is irrelevant to the pending claims or defenses between named parties in the MDL;

The request is overly broad as it seeks information beyond the relevant time, scope and subject matter of this litigation established by Centers for Disease Control and Prevention ("CDC"), which has defined the patients at risk and the products tied to the fungal meningitis outbreak to those patients injected after May 21, 2012 with three specific lots of methylprednisolone acetate ("MPA") – Lot Numbers 05212012@68, 06292012@26, and 08102012@51 – produced by the New England Compounding Center ("NECC");

The request exceeds this Court's Order which limited the Subpoena in time (January 2011 – November 2012) and scope (information relating to "these actions");

PCWF further objects to this Request to the extent it seeks documents that are not in PCWF's ownership, possession, custody or control, or that would require it to seek documents from or belonging to third parties.

Mark Zamora, Esq.
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PCWF further objects to the extent the documents and information the PSC seeks can be obtained from some other source that is more convenient, less burdensome, and/or less expensive, such as NECP, who is a party to the MDL.

PCWF further objects to this Request to the extent it fails to define various vague and ambiguous terms and conditions including, but not limited to “procurement,” “cardioplegic solution,” and “discounts applied.”

PCWF further objects to the production of ESI that is not reasonably accessible or would otherwise impose undue burden or cost to identify, collect, process, review and/or produce. In addition, PCWF objects to the extent the PSC seeks the production of ESI without: (1) any negotiated ESI protocol; (2) providing necessary clarification and appropriate limitations as to the type(s), location(s), and accessibility of the ESI requested; and/or (3) including any good-faith proposal for appropriate cost-shifting relative to PCWF’s identification, collection, review and production.

PCWF further objects to this Request to the extent it seeks to force PCWF to conduct an unreasonable, unduly burdensome search, review and production on the PSC’s behalf.

¶4 Any and all documents and/or ESI reflection, and/or related in any way whatsoever to, the procurement of ophthalmic solution from NECP during the five-year period immediately preceding October 6, 2012, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of ophthalmic solution, the cost you paid for the ophthalmic solution, applicable warranties, shelf life, expiration dates, and requirements and instructions for shipment and/or storage. Also including prescriptions submitted to NECP, prescription order forms, NECP charges for ophthalmic solution (before and after any discounts applied).

As discussed, my client, as a pain clinic, does not use ophthalmic solution.

OBJECTION: PCWF objects to ¶4 on the grounds that:

This request to a non-party is irrelevant to the pending claims or defenses between named parties in the MDL;

The request is overly broad as it seeks information beyond the relevant time, scope and subject matter of this litigation established by Centers for Disease Control and Prevention (“CDC”), which has defined the patients at risk and the products tied to the fungal meningitis outbreak to those patients injected after May 21, 2012 with three specific lots of methylprednisolone acetate (“MPA”) – Lot Numbers 05212012@68, 06292012@26, and 08102012@51 – produced by the New England Compounding Center (“NECC”);

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The request exceeds this Court's Order which limited the Subpoena in time (January 2011 – November 2012) and scope (information relating to "these actions");

PCWF further objects to this Request to the extent it seeks documents that are not in PCWF's ownership, possession, custody or control, or that would require it to seek documents from or belonging to third parties.

PCWF further objects to the extent the documents and information the PSC seeks can be obtained from some other source that is more convenient, less burdensome, and/or less expensive, such as NECP, who is a party to the MDL.

PCWF further objects to this Request to the extent it fails to define various vague and ambiguous terms and conditions including, but not limited to "procurement," "ophthalmic solution," and "discounts applied."

PCWF further objects to the production of ESI that is not reasonably accessible or would otherwise impose undue burden or cost to identify, collect, process, review and/or produce. In addition, PCWF objects to the extent the PSC seeks the production of ESI without: (1) any negotiated ESI protocol; (2) providing necessary clarification and appropriate limitations as to the type(s), location(s), and accessibility of the ESI requested; and/or (3) including any good-faith proposal for appropriate cost-shifting relative to PCWF's identification, collection, review and production.

PCWF further objects to this Request to the extent it seeks to force PCWF to conduct an unreasonable, unduly burdensome search, review and production on the PSC's behalf.

¶5 Any and all documents and/or ESI reflection, and/or related in any way whatsoever to, the procurement of preservative-free saline solution from NECP during the five-year period immediately preceding October 6, 2012, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of saline solution, the cost you paid for the saline solution, applicable warranties, shelf life, expiration dates, and requirements and instructions for shipment and/or storage. Also including prescriptions submitted to NECP, prescription order forms, NECP charges for preservative-free saline solution (before and after any discounts applied).

As discussed, my client, as a pain clinic, does not use saline solution.

OBJECTION: PCWF objects to ¶5 on the grounds that:

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This request to a non-party is irrelevant to the pending claims or defenses between named parties in the MDL;

The request is overly broad as it seeks information beyond the relevant time, scope and subject matter of this litigation established by Centers for Disease Control and Prevention ("CDC"), which has defined the patients at risk and the products tied to the fungal meningitis outbreak to those patients injected after May 21, 2012 with three specific lots of methylprednisolone acetate ("MPA") – Lot Numbers 05212012@68, 06292012@26, and 08102012@51 – produced by the New England Compounding Center ("NECC");

The request exceeds this Court's Order which limited the Subpoena in time (January 2011 – November 2012) and scope (information relating to "these actions");

PCWF further objects to this Request to the extent it seeks documents that are not in PCWF's ownership, possession, custody or control, or that would require it to seek documents from or belonging to third parties.

PCWF further objects to the extent the documents and information the PSC seeks can be obtained from some other source that is more convenient, less burdensome, and/or less expensive, such as NECP, who is a party to the MDL.

PCWF further objects to this Request to the extent it fails to define various vague and ambiguous terms and conditions including, but not limited to "complaints" "preservative-free saline," and "discounts applied."

PCWF further objects to the production of ESI that is not reasonably accessible or would otherwise impose undue burden or cost to identify, collect, process, review and/or produce. In addition, PCWF objects to the extent the PSC seeks the production of ESI without: (1) any negotiated ESI protocol; (2) providing necessary clarification and appropriate limitations as to the type(s), location(s), and accessibility of the ESI requested; and/or (3) including any good-faith proposal for appropriate cost-shifting relative to PCWF's identification, collection, review and production.

PCWF further objects to this Request to the extent it seeks to force PCWF to conduct an unreasonable, unduly burdensome search, review and production on the PSC's behalf.

¶6 Any and all documents and/or ESI reflecting, and/or related to, the identification of each and every patient that was administered an NECP product during the five-year period immediately preceding October 6, 2012, including patient name, address, date of birth, identification of product administered, and date product was administered.

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OBJECTION: PCWF objects to ¶6 on the grounds that:

This request to a non-party is irrelevant to the pending claims or defenses between named parties in the MDL;

The request is overly broad as it seeks information beyond the relevant time, scope and subject matter of this litigation established by Centers for Disease Control and Prevention ("CDC"), which has defined the patients at risk and the products tied to the fungal meningitis outbreak to those patients injected after May 21, 2012 with three specific lots of methylprednisolone acetate ("MPA") – Lot Numbers 05212012@68, 06292012@26, and 08102012@51 – produced by the New England Compounding Center ("NECC");

The request exceeds this Court's Order which limited the Subpoena in time (January 2011 – November 2012) and scope (information relating to "these actions");

PCWF further objects to this Request to the extent it seeks documents that are not in PCWF's ownership, possession, custody or control, or that would require it to seek documents from or belonging to third parties;

PCWF further objects to the extent the information the PSC seeks can be obtained from some other source that is more convenient, less burdensome, and/or less expensive.

The disclosure of a non-party patient's protected health information from a non-party medical provider to PSC would violate HIPAA, as there medical condition is not at issue in this MDL and would have to be used for purposes outside this litigation;

PSC cannot use the MDL discovery process to discover the identity of non-party patients for the purposes of adding clients;

PCWF further objects to the production of ESI that is not reasonably accessible or would otherwise impose undue burden or cost to identify, collect, process, review and/or produce. In addition, PCWF objects to the extent the PSC seeks the production of ESI without: (1) any negotiated ESI protocol; (2) providing necessary clarification and appropriate limitations as to the type(s), location(s), and accessibility of the ESI requested; and/or (3) including any good-faith proposal for appropriate cost-shifting relative to PCWF's identification, collection, review and production.

PCWF further objects to this Request to the extent that it seeks or may be deemed to seek documents or information in the public domain, or that is confidential, and/or that is protected from disclosure by the attorney-client privilege, work product doctrine, or any other privilege, immunity or limitation on discovery.

PCWF further objects to this Request to the extent it seeks to force PCWF to conduct an unreasonable, unduly burdensome search, review and production on the PSC's behalf.

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¶7 Any and all documents and/or ESI reflecting or containing communications (written or otherwise) between PAIN CONSULTANTS OF WEST FLORIDA ("Healthcare Provider"), its employees, principals, partners, and/or agents, and NECP, its employees and/or agents, during the five-year period immediately preceding October 6, 2012, including, but not limited to, any complaints or adverse event reports made to NECP by the Healthcare Provider.

OBJECTION: PCWF objects to ¶7 on the grounds that:

This request to a non-party is irrelevant to the pending claims or defenses between named parties in the MDL;

The request is overly broad as it seeks information beyond the relevant time, scope and subject matter of this litigation established by Centers for Disease Control and Prevention ("CDC"), which has defined the patients at risk and the products tied to the fungal meningitis outbreak to those patients injected after May 21, 2012 with three specific lots of methylprednisolone acetate ("MPA") – Lot Numbers 05212012@68, 06292012@26, and 08102012@51 – produced by the New England Compounding Center ("NECC");

The request exceeds this Court's Order which limited the Subpoena in time (January 2011 – November 2012) and scope (information relating to "these actions");

PCWF further objects to this Request to the extent it seeks documents that are not in PCWF's ownership, possession, custody or control, or that would require it to seek documents from or belonging to third parties.

PCWF further objects to the extent the documents and information the PSC seeks can be obtained from some other source that is more convenient, less burdensome, and/or less expensive, such as NECP, who is a party to the MDL.

PCWF further objects to this Request to the extent it fails to define various vague and ambiguous terms and conditions including, but not limited to "complaints" "adverse event reports."

PCWF further objects to the production of ESI that is not reasonably accessible or would otherwise impose undue burden or cost to identify, collect, process, review and/or produce. In addition, PCWF objects to the extent the PSC seeks the production of ESI without: (1) any negotiated ESI protocol; (2) providing necessary clarification and appropriate limitations as to the type(s), location(s), and accessibility of the ESI requested; and/or (3)

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including any good-faith proposal for appropriate cost-shifting relative to PCWF's identification, collection, review and production.

PCWF further objects to this Request to the extent that it seeks or may be deemed to seek documents or information in the public domain, or that is confidential, and/or that is protected from disclosure by the attorney-client privilege, work product doctrine, or any other privilege, immunity or limitation on discovery.

PCWF further objects to this Request to the extent it seeks to force PCWF to conduct an unreasonable, unduly burdensome search, review and production on the PSC's behalf.

¶8 Any and all documents and/or ESI reflecting or containing information obtained by the Healthcare Provider, its employees and/or agents, regarding NECP, including without limitation of the foregoing, NECP's qualifications, certifications or accreditations, or lack thereof, regulatory compliance, lack of regulatory compliance, operations, enforcement actions, suitability for conducting its business, legal actions and/or warnings, brochures, policies and procedures, ordering and delivery information company overviews, standard operating procedures, executive summaries, attachments A, B or others (relating to HIPAA, NECP policies and procedures, or other information).

OBJECTION: PCWF objects to ¶8 on the grounds that:

This request to a non-party is irrelevant to the pending claims or defenses between named parties in the MDL;

The request is overly broad as it seeks information beyond the relevant time, scope and subject matter of this litigation established by Centers for Disease Control and Prevention ("CDC"), which has defined the patients at risk and the products tied to the fungal meningitis outbreak to those patients injected after May 21, 2012 with three specific lots of methylprednisolone acetate ("MPA") – Lot Numbers 05212012@68, 06292012@26, and 08102012@51 – produced by the New England Compounding Center ("NECC");

The request exceeds this Court's Order which limited the Subpoena in time (January 2011 – November 2012) and scope (information relating to "these actions");

PCWF further objects to this Request to the extent it seeks documents that are not in PCWF's ownership, possession, custody or control, or that would require it to seek documents from or belonging to third parties.

PCWF further objects to the extent the documents and information the PSC seeks can be obtained from some other source that is more convenient, less burdensome, and/or less expensive, such as NECP, who is a party to the MDL.

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PCWF further objects to this Request to the extent it fails to define various vague and ambiguous terms and conditions including, but not limited to “NECP’s qualifications,” “regulatory compliance,” “lack of regulatory compliance,” “operations,” “enforcement actions,” “suitability for conducting its business,” “policies and procedures,” “company overviews,” “standard operating procedures,” and “executive summaries.”

PCWF further objects to the production of ESI that is not reasonably accessible or would otherwise impose undue burden or cost to identify, collect, process, review and/or produce. In addition, PCWF objects to the extent the PSC seeks the production of ESI without: (1) any negotiated ESI protocol; (2) providing necessary clarification and appropriate limitations as to the type(s), location(s), and accessibility of the ESI requested; and/or (3) including any good-faith proposal for appropriate cost-shifting relative to PCWF’s identification, collection, review and production.

PCWF further objects to this Request to the extent it seeks to force PCWF to conduct an unreasonable, unduly burdensome search, review and production on the PSC’s behalf. This particular request does not even have a time period during which the documents are requested.

¶9 Any and all documents and/or ESI reflecting or containing information obtained by, or communications received by, the Healthcare Provider, its employees and/or agents, concerning the fitness of any products purchased or obtained from NECP for their intended use, during the five-year period immediately preceding October 6, 2012, including but not limited to any environmental testing results, microbiology reports or certificates of analysis.

OBJECTION: PCWF objects to ¶9 on the grounds that:

This request to a non-party is irrelevant to the pending claims or defenses between named parties in the MDL;

The request is overly broad as it seeks information beyond the relevant time, scope and subject matter of this litigation established by Centers for Disease Control and Prevention (“CDC”), which has defined the patients at risk and the products tied to the fungal meningitis outbreak to those patients injected after May 21, 2012 with three specific lots of methylprednisolone acetate (“MPA”) – Lot Numbers 05212012@68, 06292012@26, and 08102012@51 – produced by the New England Compounding Center (“NECC”);

The request exceeds this Court’s Order which limited the Subpoena in time (January 2011 – November 2012) and scope (information relating to “these actions”);

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PCWF further objects to this Request to the extent it seeks documents that are not in PCWF's ownership, possession, custody or control, or that would require it to seek documents from or belonging to third parties.

PCWF further objects to the extent the documents and information the PSC seeks can be obtained from some other source that is more convenient, less burdensome, and/or less expensive, such as NECP, who is a party to the MDL.

PCWF further objects to this Request to the extent it fails to define various vague and ambiguous terms and conditions including, but not limited to "fitness of any products," "intended use," "environmental testing results," "microbiology reports," and "certificates of analysis."

PCWF further objects to the production of ESI that is not reasonably accessible or would otherwise impose undue burden or cost to identify, collect, process, review and/or produce. In addition, PCWF objects to the extent the PSC seeks the production of ESI without: (1) any negotiated ESI protocol; (2) providing necessary clarification and appropriate limitations as to the type(s), location(s), and accessibility of the ESI requested; and/or (3) including any good-faith proposal for appropriate cost-shifting relative to PCWF's identification, collection, review and production.

PCWF further objects to this Request to the extent it seeks to force PCWF to conduct an unreasonable, unduly burdensome search, review and production on the PSC's behalf.

¶10 Any and all documents and/or ESI reflecting or containing information obtained by, or sent to, the Healthcare Provider, its employees and/agents, from the Centers for Disease Control and Prevention, the Federal Food and Drug Administration, and/or any other Federal, state or local regulatory agency, concerning the fitness of any products manufactured, compounded or produced by NECP for their intended purpose.

OBJECTION: PCWF objects to ¶10 on the grounds that:

This request to a non-party is irrelevant to the pending claims or defenses between named parties in the MDL;

The request is overly broad as it seeks information beyond the relevant time, scope and subject matter of this litigation established by Centers for Disease Control and Prevention ("CDC"), which has defined the patients at risk and the products tied to the fungal meningitis outbreak to those patients injected after May 21, 2012 with three specific lots of methylprednisolone acetate ("MPA") – Lot Numbers 05212012@68, 06292012@26, and 08102012@51 – produced by the New England Compounding Center ("NECC");

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The request exceeds this Court's Order which limited the Subpoena in time (January 2011 – November 2012) and scope (information relating to "these actions");

PCWF further objects to this Request to the extent it seeks documents that are not in PCWF's ownership, possession, custody or control, or that would require it to seek documents from or belonging to third parties.

PCWF further objects to the extent the documents and information the PSC seeks can be obtained from some other source that is more convenient, less burdensome, and/or less expensive, such as the FDA or CDC.

PCWF further objects to this Request to the extent it fails to define various vague and ambiguous terms and conditions including, but not limited to "other Federal state or local regulatory agency," "fitness of any products," and "intended purpose."

PCWF further objects to the production of ESI that is not reasonably accessible or would otherwise impose undue burden or cost to identify, collect, process, review and/or produce. In addition, PCWF objects to the extent the PSC seeks the production of ESI without: (1) any negotiated ESI protocol; (2) providing necessary clarification and appropriate limitations as to the type(s), location(s), and accessibility of the ESI requested; and/or (3) including any good-faith proposal for appropriate cost-shifting relative to PCWF's identification, collection, review and production.

PCWF further objects to this Request to the extent it seeks to force PCWF to conduct an unreasonable, unduly burdensome search, review and production on the PSC's behalf. This particular request does not even have a time period during which the documents are requested.

¶11 Any and all documents and/or ESI reflecting or containing communications between the Healthcare Provider and any federal or state agency (including, but not limited to state licensing authorities, the Food and Drug Administration, and the Centers for Disease Control and Prevention) in connection with the procurement of products from any compounding pharmacy.

OBJECTION: PCWF objects to ¶11 on the grounds that PCWF's communications to regulatory agencies regarding other non-party pharmacies is wholly irrelevant to parties' pending claims in this MDL.

The request is overly broad as it seeks information beyond the relevant time, scope and subject matter of this litigation established by Centers for Disease Control and Prevention ("CDC"), which has defined the patients at risk and the products tied to the fungal meningitis outbreak to those patients injected after May 21, 2012 with three specific lots of

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methylprednisolone acetate ("MPA") – Lot Numbers 05212012@68, 06292012@26, and 08102012@51 – produced by the New England Compounding Center ("NECC");

The request exceeds this Court's Order which limited the Subpoena in time (January 2011 – November 2012) and scope (information relating to "these actions");

PCWF further objects to this Request to the extent it seeks documents that are not in PCWF's ownership, possession, custody or control, or that would require it to seek documents from or belonging to third parties.

PCWF further objects to the extent the documents and information the PSC seeks can be obtained from some other source that is more convenient, less burdensome, and/or less expensive, such as the FDA or CDC.

PCWF further objects to this Request to the extent it fails to define various vague and ambiguous terms and conditions including, but not limited to "other Federal state or local regulatory agency," "procurement."

PCWF further objects to the production of ESI that is not reasonably accessible or would otherwise impose undue burden or cost to identify, collect, process, review and/or produce. In addition, PCWF objects to the extent the PSC seeks the production of ESI without: (1) any negotiated ESI protocol; (2) providing necessary clarification and appropriate limitations as to the type(s), location(s), and accessibility of the ESI requested; and/or (3) including any good-faith proposal for appropriate cost-shifting relative to PCWF's identification, collection, review and production.

PCWF further objects to this Request to the extent it seeks to force PCWF to conduct an unreasonable, unduly burdensome search, review and production on the PSC's behalf. This particular request does not even have a time period during which the documents are requested.

¶12 Any and all documents and/or ESI reflecting or containing marketing information from NECP, NECP's agents, or any sales company or person marketing, selling, or attempting to sell products on behalf of NECP.

OBJECTION: PCWF objects to ¶12 on the grounds that:

This request to a non-party is irrelevant to the pending claims or defenses between named parties in the MDL;

The request is overly broad as it seeks information beyond the relevant time, scope and subject matter of this litigation established by Centers for Disease Control and Prevention ("CDC"), which has defined the patients at risk and the products tied to the fungal

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meningitis outbreak to those patients injected after May 21, 2012 with three specific lots of methylprednisolone acetate ("MPA") – Lot Numbers 05212012@68, 06292012@26, and 08102012@51 – produced by the New England Compounding Center ("NECC");

The request exceeds this Court's Order which limited the Subpoena in time (January 2011 – November 2012) and scope (information relating to "these actions");

PCWF further objects to this Request to the extent it seeks documents that are not in PCWF's ownership, possession, custody or control, or that would require it to seek documents from or belonging to third parties.

PCWF further objects to the extent the documents and information the PSC seeks can be obtained from some other source that is more convenient, less burdensome, and/or less expensive.

PCWF further objects to this Request to the extent it fails to define various vague and ambiguous terms and conditions including, but not limited to "sales company," or "person marketing, selling or attempting to sell products on behalf of NECP."

PCWF further objects to the production of ESI that is not reasonably accessible or would otherwise impose undue burden or cost to identify, collect, process, review and/or produce. In addition, PCWF objects to the extent the PSC seeks the production of ESI without: (1) any negotiated ESI protocol; (2) providing necessary clarification and appropriate limitations as to the type(s), location(s), and accessibility of the ESI requested; and/or (3) including any good-faith proposal for appropriate cost-shifting relative to PCWF's identification, collection, review and production.

PCWF further objects to this Request to the extent it seeks to force PCWF to conduct an unreasonable, unduly burdensome search, review and production on the PSC's behalf. This particular request does not even have a time period during which the documents are requested.

¶13 Any and all documents and/or ESI reflecting or containing agreements, contracts and/or warranties between the Healthcare Provider and NECP, NECP's agents, or any sales company or person marketing, selling, or attempting to sell products on behalf of NECP.

OBJECTION: PCWF objects to ¶13 on the grounds that:

This request to a non-party is irrelevant to the pending claims or defenses between named parties in the MDL;

The request is overly broad as it seeks information beyond the relevant time, scope and subject matter of this litigation established by Centers for Disease Control and Prevention

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(“CDC”), which has defined the patients at risk and the products tied to the fungal meningitis outbreak to those patients injected after May 21, 2012 with three specific lots of methylprednisolone acetate (“MPA”) – Lot Numbers 05212012@68, 06292012@26, and 08102012@51 – produced by the New England Compounding Center (“NECC”);

The request exceeds this Court’s Order which limited the Subpoena in time (January 2011 – November 2012) and scope (information relating to “these actions”);

PCWF further objects to this Request to the extent it seeks documents that are not in PCWF’s ownership, possession, custody or control, or that would require it to seek documents from or belonging to third parties.

PCWF further objects to the extent the documents and information the PSC seeks can be obtained from some other source that is more convenient, less burdensome, and/or less expensive, such as NECP, who is a party to the MDL.

PCWF further objects to this Request to the extent it fails to define various vague and ambiguous terms and conditions including, but not limited to “reflecting or containing agreements,” “contracts,” “warranties,” “sales company,” and “person marketing, selling or attempting to sell products on behalf of NECP.”

PCWF further objects to the production of ESI that is not reasonably accessible or would otherwise impose undue burden or cost to identify, collect, process, review and/or produce. In addition, PCWF objects to the extent the PSC seeks the production of ESI without: (1) any negotiated ESI protocol; (2) providing necessary clarification and appropriate limitations as to the type(s), location(s), and accessibility of the ESI requested; and/or (3) including any good-faith proposal for appropriate cost-shifting relative to PCWF’s identification, collection, review and production.

PCWF further objects to this Request to the extent it seeks to force PCWF to conduct an unreasonable, unduly burdensome search, review and production on the PSC’s behalf. This particular request does not even have a time period during which the documents are requested.

¶14 Any and all documents and/or ESI reflecting or containing recall notices received by the Healthcare Provider pertaining to products produced by NECP, including without limitation of the foregoing, the date, time and manner of receipt of the recall notices, the specific person or persons within the Healthcare Provider who received the notice, and the substance of the notice.

OBJECTION: PCWF objects to ¶14 on the grounds that:

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This request to a non-party is irrelevant to the pending claims or defenses between named parties in the MDL;

The request is overly broad as it seeks information beyond the relevant time, scope and subject matter of this litigation established by Centers for Disease Control and Prevention ("CDC"), which has defined the patients at risk and the products tied to the fungal meningitis outbreak to those patients injected after May 21, 2012 with three specific lots of methylprednisolone acetate ("MPA") – Lot Numbers 05212012@68, 06292012@26, and 08102012@51 – produced by the New England Compounding Center ("NECC");

The request exceeds this Court's Order which limited the Subpoena in time (January 2011 – November 2012) and scope (information relating to "these actions");

PCWF further objects to this Request to the extent it seeks documents that are not in PCWF's ownership, possession, custody or control, or that would require it to seek documents from or belonging to third parties.

PCWF further objects to the extent the documents and information the PSC seeks can be obtained from some other source that is more convenient, less burdensome, and/or less expensive, such as NECP, who is a party to the MDL.

PCWF further objects to this Request to the extent it fails to define various vague and ambiguous terms and conditions including, but not limited to "reflecting or containing recall notices" and "products produced by NECP."

PCWF further objects to the production of ESI that is not reasonably accessible or would otherwise impose undue burden or cost to identify, collect, process, review and/or produce. In addition, PCWF objects to the extent the PSC seeks the production of ESI without: (1) any negotiated ESI protocol; (2) providing necessary clarification and appropriate limitations as to the type(s), location(s), and accessibility of the ESI requested; and/or (3) including any good-faith proposal for appropriate cost-shifting relative to PCWF's identification, collection, review and production.

PCWF further objects to this Request to the extent it seeks to force PCWF to conduct an unreasonable, unduly burdensome search, review and production on the PSC's behalf. This particular request does not even have a time period during which the documents are requested.

¶15 Any and all documents and/or ESI reflecting or contacting communications made or issued by the Healthcare Provider, its employees and/or agents, in response to any recall notice regarding NECP products, including without limitation of the foregoing, the date, time and manner of transmission of the communication, the person(s) to which the communication was directed, and the person

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at the Healthcare Provider who made or delivered the communication.

OBJECTION: PCWF objects to ¶15 on the grounds that:

This request to a non-party is irrelevant to the pending claims or defenses between named parties in the MDL;

The request is overly broad as it seeks information beyond the relevant time, scope and subject matter of this litigation established by Centers for Disease Control and Prevention ("CDC"), which has defined the patients at risk and the products tied to the fungal meningitis outbreak to those patients injected after May 21, 2012 with three specific lots of methylprednisolone acetate ("MPA") – Lot Numbers 05212012@68, 06292012@26, and 08102012@51 – produced by the New England Compounding Center ("NECC");

The request exceeds this Court's Order which limited the Subpoena in time (January 2011 – November 2012) and scope (information relating to "these actions");

PCWF further objects to this Request to the extent it seeks documents that are not in PCWF's ownership, possession, custody or control, or that would require it to seek documents from or belonging to third parties.

PCWF further objects to the extent the documents and information the PSC seeks can be obtained from some other source that is more convenient, less burdensome, and/or less expensive, such as NECP, who is a party to the MDL.

PCWF further objects to this Request to the extent it fails to define various vague and ambiguous terms and conditions including, but not limited to "recall notice" and "manner of transmission."

PCWF further objects to the production of ESI that is not reasonably accessible or would otherwise impose undue burden or cost to identify, collect, process, review and/or produce. In addition, PCWF objects to the extent the PSC seeks the production of ESI without: (1) any negotiated ESI protocol; (2) providing necessary clarification and appropriate limitations as to the type(s), location(s), and accessibility of the ESI requested; and/or (3) including any good-faith proposal for appropriate cost-shifting relative to PCWF's identification, collection, review and production.

PCWF further objects to this Request to the extent it seeks to force PCWF to conduct an unreasonable, unduly burdensome search, review and production on the PSC's behalf. This particular request does not even have a time period during which the documents are requested.

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¶16 Any and all documents regarding any investigation or inquiry the Healthcare Provider performed related to attempts by NECP to comply with UPS 797.

OBJECTION: PCWF objects to ¶16 on the grounds that:

This request to a non-party is irrelevant to the pending claims or defenses between named parties in the MDL;

The request is overly broad as it seeks information beyond the relevant time, scope and subject matter of this litigation established by Centers for Disease Control and Prevention ("CDC"), which has defined the patients at risk and the products tied to the fungal meningitis outbreak to those patients injected after May 21, 2012 with three specific lots of methylprednisolone acetate ("MPA") – Lot Numbers 05212012@68, 06292012@26, and 08102012@51 – produced by the New England Compounding Center ("NECC");

The request exceeds this Court's Order which limited the Subpoena in time (January 2011 – November 2012) and scope (information relating to "these actions");

PCWF further objects to this Request to the extent it seeks documents that are not in PCWF's ownership, possession, custody or control, or that would require it to seek documents from or belonging to third parties.

PCWF further objects to the extent the documents and information the PSC seeks can be obtained from some other source that is more convenient, less burdensome, and/or less expensive, such as NECP, who is a party to the MDL.

PCWF further objects to this Request to the extent it fails to define various vague and ambiguous terms and conditions including, but not limited to "investigation or inquiry" and "United States Pharmacopeia National Formulary."

PCWF further objects to the production of ESI or other documents that are not reasonably accessible or would otherwise impose undue burden or cost to identify, collect, process, review and/or produce. In addition, PCWF objects to the extent the PSC seeks the production of ESI without: (1) any negotiated ESI protocol; (2) providing necessary clarification and appropriate limitations as to the type(s), location(s), and accessibility of the ESI requested; and/or (3) including any good-faith proposal for appropriate cost-shifting relative to PCWF's identification, collection, review and production.

PCWF further objects to this Request to the extent it seeks to force PCWF to conduct an unreasonable, unduly burdensome search, review and production on the PSC's behalf.

PCWF further objects to this Request to the extent it seeks to force PCWF to conduct an unreasonable, unduly burdensome search, review and production on the PSC's behalf.

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This particular request does not even have a time period during which the documents are requested.

¶17 Any and all policies of insurance, including without limitation of the foregoing, professional liability, malpractice, products liability, general liability, and comprehensive or umbrella policies, issued to the Healthcare Provider and/or its principal officers and directors and/or any physician working for or on behalf of the Healthcare Provider, for the policy periods including calendar years 2011, 2012 and 2013.

OBJECTION: PCWF objects to ¶17 on the grounds that:

This request to a non-party is wholly irrelevant, as the information requested has no bearing on the parties' pending claims in this MDL;

The request is overly broad as it seeks information beyond the relevant time, scope and subject matter of this litigation established by Centers for Disease Control and Prevention ("CDC"), which has defined the patients at risk and the products tied to the fungal meningitis outbreak to those patients injected after May 21, 2012 with three specific lots of methylprednisolone acetate ("MPA") – Lot Numbers 05212012@68, 06292012@26, and 08102012@51 – produced by the New England Compounding Center ("NECC");

The request exceeds this Court's Order which limited the Subpoena in time (January 2011 – November 2012) and scope (information relating to "these actions");

PCWF further objects to this Request to the extent it seeks documents that are not in PCWF's ownership, possession, custody or control, or that would require it to seek documents from or belonging to third parties;

¶18 Articles of Incorporation and/or By-Laws applicable to the Healthcare Provider for calendar years 2011, 2012 and 2013.

OBJECTION: PCWF objects to ¶18 on the grounds that:

This request to a non-party is wholly irrelevant, as the information requested has no bearing on the parties' pending claims in this MDL;

The request is overly broad as it seeks information beyond the relevant time, scope and subject matter of this litigation established by Centers for Disease Control and Prevention ("CDC"), which has defined the patients at risk and the products tied to the fungal meningitis outbreak to those patients injected after May 21, 2012 with three specific lots of methylprednisolone acetate ("MPA") – Lot Numbers 05212012@68, 06292012@26, and 08102012@51 – produced by the New England Compounding Center ("NECC");

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The request exceeds this Court's Order which limited the Subpoena in time (January 2011 – November 2012) and scope (information relating to "these actions");

¶19 Any and all documents and/or ESI reflecting or containing the names, addresses and positions (President, Vice-President, Director, etc.) within the Healthcare Provider of all officers and directors of the Healthcare Provider during the calendar years 2011, 2012 and 2013.

OBJECTION: PCWF objects to ¶19 on the grounds that:

This request to a non-party is wholly irrelevant, as the information requested has no bearing on the parties' pending claims in this MDL;

The request is overly broad as it seeks information beyond the relevant time, scope and subject matter of this litigation established by Centers for Disease Control and Prevention ("CDC"), which has defined the patients at risk and the products tied to the fungal meningitis outbreak to those patients injected after May 21, 2012 with three specific lots of methylprednisolone acetate ("MPA") – Lot Numbers 05212012@68, 06292012@26, and 08102012@51 – produced by the New England Compounding Center ("NECC");

The request exceeds this Court's Order which limited the Subpoena in time (January 2011 – November 2012) and scope (information relating to "these actions");

¶20 Any and all documents showing the entities or individuals with an ownership interest in the Healthcare Provider.

OBJECTION: PCWF objects to ¶20 on the grounds that this request:

This request to a non-party is wholly irrelevant, as the information requested has no bearing on the parties' pending claims in this MDL;

The request is overly broad as it seeks information beyond the relevant time, scope and subject matter of this litigation established by Centers for Disease Control and Prevention ("CDC"), which has defined the patients at risk and the products tied to the fungal meningitis outbreak to those patients injected after May 21, 2012 with three specific lots of methylprednisolone acetate ("MPA") – Lot Numbers 05212012@68, 06292012@26, and 08102012@51 – produced by the New England Compounding Center ("NECC");

The request exceeds this Court's Order which limited the Subpoena in time (January 2011 – November 2012) and scope (information relating to "these actions");

¶21 Any and all organizational charts maintained by the Healthcare Provider and/or any documents listing directors, officers, employees,

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and/or agents of the Healthcare Provider showing the names and positions of said directors, officers, employees, and/or agents and their relationship or rank within the Healthcare Provider.

OBJECTION: PCWF objects to ¶21 on the grounds that:

This request to a non-party is wholly irrelevant, as the information requested has no bearing on the parties' pending claims in this MDL;


The request is overly broad as it seeks information beyond the relevant time, scope and subject matter of this litigation established by Centers for Disease Control and Prevention ("CDC"), which has defined the patients at risk and the products tied to the fungal meningitis outbreak to those patients injected after May 21, 2012 with three specific lots of methylprednisolone acetate ("MPA") – Lot Numbers 05212012@68, 06292012@26, and 08102012@51 – produced by the New England Compounding Center ("NECC");

The request exceeds this Court's Order which limited the Subpoena in time (January 2011 – November 2012) and scope (information relating to "these actions");

Based on the information contained in this letter, on behalf of PCWF, we object to the Subpoena and plan to file a Motion to Quash setting forth these objections. Based on these objections, we will not be producing a designated corporate representative for deposition on August 2, 2013 or producing any documents in response to this subpoena. We remain ready and willing to discuss these issues with you over the telephone.

Sincerely,

FULLER, MITCHELL, HOOD
& STEPHENS, LLC



Halley M. Stephens
For the Firm

FULLER, MITCHELL, HOOD & STEPHENS, LLC

LAWYERS
2565 Barrington Circle
Tallahassee, FL 32308
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FACSIMILE COVER SHEET

To	Company	Number
Mark Zamora		404.506.9223

FROM: Halley M. Stephens

DATE: July 15, 2013

NO. OF PAGES: _23 _(INCLUDING COVER SHEET)

RE: NECC

MESSAGE: Please see attached correspondence.

If you do not receive all the pages of this fax, please call 850.222.0770

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Mark Zamora, Esq.
July 15, 2013
Page 23

bcc: Tamara Martin, Practice Manager (by email only)
Rebecca Pehlke, AIC, CPCU (by email only)